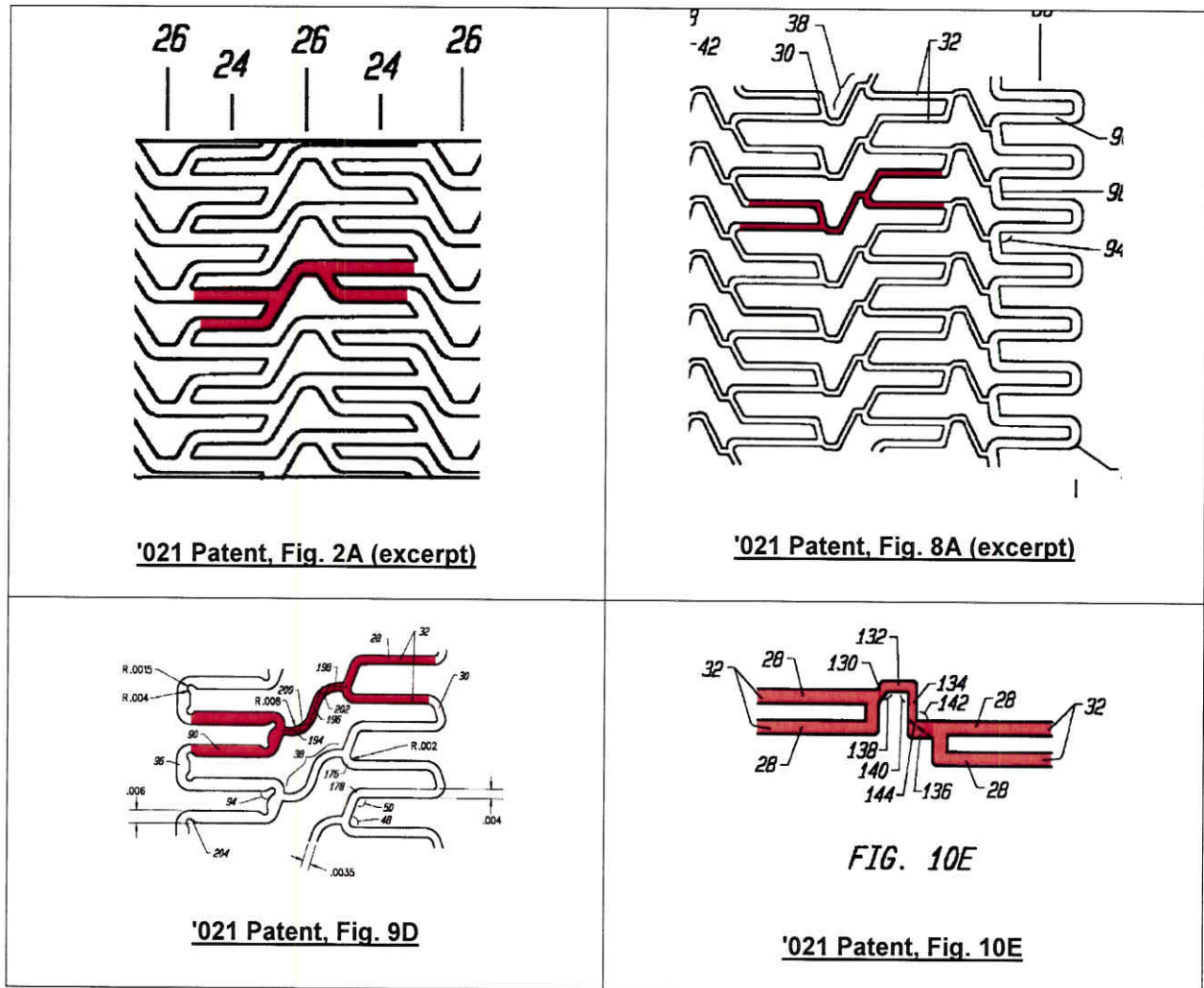


Every embodiment shown in the '021 specification has this kind of "split level" connection" between "circumferentially offset expansion strut pairs." Every embodiment shows a design in which the "first expansion strut" of each connected strut pair is offset from each other. E.g.:



None of those figures shows "expansion strut pairs" in adjacent "expansion columns" that are aligned and face in opposite directions, as is the case with 180 degree out-of-phase designs. Here, as in Nystrom, there is "nothing" in the specification "to support the conclusion that a skilled artisan would have construed the ['wherein' clause]" to cover such designs. Nystrom, 424 F.3d at 1145. Nothing in the specification (including the provisional

application, which it incorporates by reference) suggests the stated objects of the invention could be achieved by using a "conventional" stent design in which the "expansion strut pairs" in adjacent expansion columns are directly aligned and face in opposite directions, in a 180 degree out-of-phase design. Indeed, Dr. Jang derided such designs as "conventional."⁴ These facts weigh heavily in favor of Conor's proposed construction. See Old Town Canoe, 448 F.3d at 1317 (construing "the completion of coalescence" to require progress of coalescence to the optimum state where "[n]othing in the written description suggests that to achieve the stated objects of the invention ... coalescence could or should be stopped at some unspecified point prior to the optimum conclusion of the process."); Abraxis Bioscience, Inc. v. Mayne Pharma, Inc., 467 F.3d 1370, 1378 (Fed. Cir. 2006) (limiting construction of "edetate" to derivatives identified in the specification).

3. Jang's Amendment and Arguments During Prosecution

Jang's first set of proposed claims based on this specification, incorporating the provisional application, was rejected and the "wherein" clause was added to overcome the rejection. The addition of the "wherein" clause during prosecution makes it clear that it was intended to limit the independent claims to precisely what Dr. Jang had claimed to invent, a stent with offset connected strut pairs.

(a) The Initial Office Action

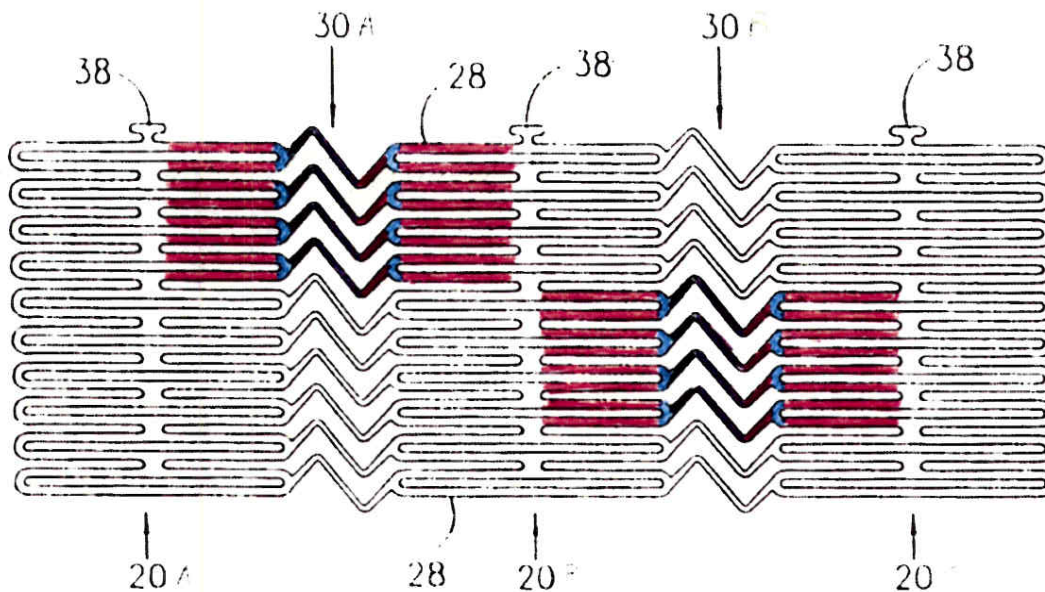
Jang initially tried to obtain broad claims that were not limited to stents with a "split level" connection scheme. Thus, his original claims were broad enough to read on stents

⁴ One of the prior art designs that the '021 specification criticizes is the so-called "Brun patent [sic]," WO 96/03092. '021 patent at 2:36-37. (In fact, Heidi Brun was the attorney for the inventors, Henry Israel and Gregory Pinchasik. See Ex. I hereto.) Dr. Jang describes the "Brun" reference as having "meander pattern[s] [i.e., expansion columns]" that are "180 degrees out of phase." '021 patent at 2:40-44. The '021 specification criticizes this and "other conventional stent designs [as] suffer[ing] in varying degrees from a variety of drawbacks" (id. at 2:57-65) that the invention is designed to overcome.

(including stents in the prior art) in which the connectors link "expansion strut pairs" with aligned first expansion struts, having a 180 degree out-of-phase pattern. In addition, his original claims did not require what BSC now calls a "curvy" connector. Instead, his original claims required a connector in three parts, but did not preclude the three parts from being aligned.

The Examiner rejected these broad original claims in the initial Office Action as anticipated by EP 0 709 067 A2 to Pinchasik. JFH 192.

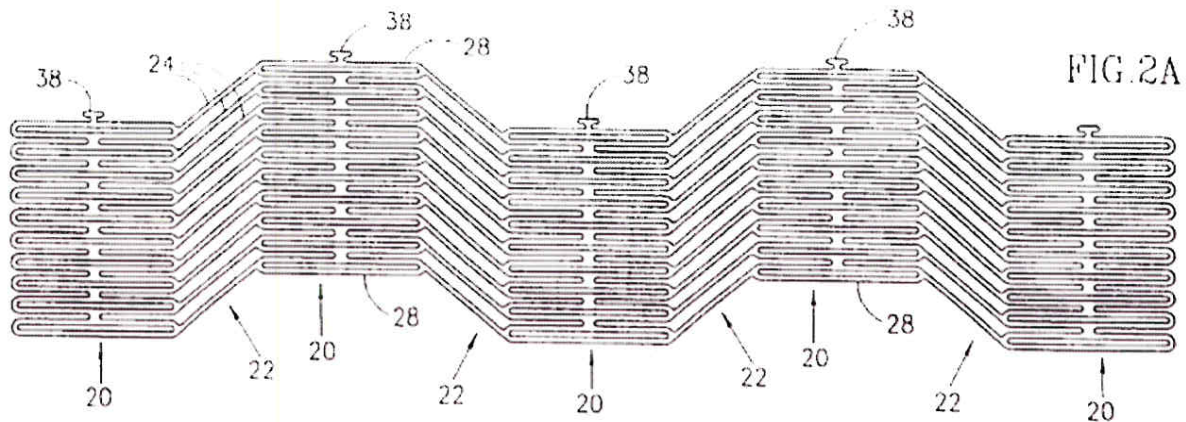
To illustrate how Pinchasik anticipated the independent claims (application claims 1 and 24), the Examiner attached Fig. 2B from Pinchasik to the initial Office Action, and colored Pinchasik's "expansion struts" pink, colored the "joining struts [crowns]" blue, and used darker color for the three sections of the connecting struts (JFH 196). As is clear from the Examiner's coloring, the connected strut pairs of the Pinchasik reference are collinear (and 180 degrees out-of-phase), with the first expansion struts of each pair aligned with one another, rather than offset.



EP 0 709 067 A2 (Pinchasik), Fig. 2B, as colored-coded by the Examiner

In addition, the Examiner rejected application claim 2 as anticipated by Pinchasik. Application claim 2 was a dependent claim that recited the stent of claim 1, with additional

language that tracks the language of the "wherein" clause that is now found in both independent claims (issued claims 1 and 23). Thus, application claim 2 recited "[t]he stent of claim 1, wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column." In rejecting application claim 2 for anticipation under § 103, the Examiner relied on Fig. 2A of Pinchasik, which is shown below. JFH 193. Here the connected strut pairs are offset, but the connector, even though straight, met the definition of the three part connector contained in the original claims.



EP 0 709 067 A2 (Pinchasik), Fig. 2A

(b) The Office Interview

Following the anticipation rejection, Jang requested an interview with the Examiner. See JFH 200. In the interview, only one reference was discussed – Pinchasik's U.S. Patent No. 5,449,373 (Ex. J). During the interview, Jang's counsel showed the Examiner a proposed amendment, which – in the Examiner's view – "appear[ed] to distinguish applicant's invention over the art of record [*i.e.*, Pinchasik]." JFH 200 (emphasis added). The Examiner

encouraged Jang "to submit the proposed language" to both of his independent claims "in a formal amendment." Id.

(c) **Jang's Amendment to Avoid Pinchasik and
His Arguments Based on that Amendment**

On June 22, 1998, Jang submitted an amendment in which he cancelled application claim 2 and made two changes in his independent claims. First, Jang added language to both independent requiring that the "intermediate section" of the connecting struts be "non-parallel" to the connecting struts' proximal and distal section. JFH 205, 208. This distinguished the connector over the straight connector shown in Pinchasik Figure 2. Second, he added the "wherein" clause at the end of both claims (id.):

wherein the first expansion strut of the first expansion strut pair in the first expansion column has a longitudinal axis offset from a longitudinal axis of the first expansion strut of the second expansion strut pair in the second expansion column.

Referring to both independent claims as "the present invention," Jang argued that the language of his amendments distinguished over both embodiments of Pinchasik (JFH 209):

Claims 1-3, 5, 7-18, 21, 24-30, 39-45, 48-50, 52-58, 60-62, 64, 66-73, 76 and 79 [including independent application claims 1 and 24, now issued claims 1 and 23] have been rejected under 35 U.S.C. § 102(b) as anticipated by EP 07067A2 ("Pinchasik, et al.).... These grounds of rejection are respectfully traversed.

The present invention is a stent with a first connecting strut with proximal, distal and intermediate sections. The intermediate section is non-parallel to the proximal and distal sections. Additionally, the stent ***has a first expansion strut of a first expansion strut pair in a first expansion column that has a longitudinal axis which is offset from a longitudinal axis of a first expansion strut of the second expansion strut pair in a second expansion column. Pinchasik et al., fails to teach or suggest such a structure. (Emphasis added)***

Notably, this argument tracks Jang's earlier disclosure of the "key" to his invention – a pair of connected strut pairs whose first expansion struts are circumferentially

offset from one another, creating a split level design. Consistent with precisely what he had invented, Jang represented that the additional requirement of a multi-part connector and the presence of the "wherein" clause distinguished Pinchasik for purposes of "[t]he present invention," i.e., for all the recited claims, including the two independent claims. At no time did he suggest that the clause has a different effect in one independent claim than in the other.

Jang's arguments distinguishing Pinchasik in reliance on the amendments limit the scope of both of his independent claims. It is well settled that a patentee "may not state during prosecution that the claims do not cover a particular device and then change position and later sue a party who makes that same device for infringement." Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 995 (Fed. Cir. 2003). The prosecution history thus "limits the ... claim[s] so as to exclude any interpretation that was disclaimed during [the] prosecution." Id. at 994 (citations omitted). The reason for this rule is straightforward: "[B]y distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, [and] he is by implication surrendering such protection." Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed. Cir. 1997).

When Jang relied on the "wherein" clause in distinguishing Pinchasik, he did not differentiate between independent claims 1 and 23 (application claim 24 became issued claim 23). Instead, he treated his disclaimer as applicable to both of his independent claims, and argued broadly that Pinchasik "fails to teach or suggest" the stent of "the present invention." Id. Absent any suggestion that the disclaimer only applied to independent claim 1, it is fully applicable to both of his independent claims. Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1347 (Fed. Cir. 1998) ("Absent qualifying language in the remarks, arguments made to obtain the allowance of one claim are relevant [in] interpreting other claims in the same

patent."); Southwall Technologies, Inc. v. Cardinal IG Co., 54 F.3d 1570, 1579 (Fed. Cir. 1995) (same). Any other result "would undercut the public's reliance on a statement in the public record and upon which reasonable competitors formed their business strategies." Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222 F.3d 951, 957 (Fed. Cir. 2000).

4. The Examiner's Understanding of Jang's Independent Claims

The Examiner clearly understood Dr. Jang's claims – all of them – to be limited to connected offset strut pairs. Two episodes in the file history illustrate the Examiner's understanding of Jang's independent claims 1 and 23. This first episode involved the Examiner's issuance of a double patenting rejection. The second episode is reflected in the Examiner's Search Notes and involved the Examiner's effort to determine whether the provisional application disclosed stents with "offset" expansion strut pairs, which would entitle the independent claims to an earlier priority date than a reference that the Examiner had discovered during a search. Both episodes show that the Examiner understood Jang's independent claims as limited to stents in which the expansion strut pairs in adjacent columns are offset and non-aligned, thus limiting the invention to Dr. Jang's "split level" design and excluding stents with a 180 degree out-of-phase design.

(a) The Double Patenting Rejection

After Jang filed the amendment adding the "wherein" clause to his independent claim, the Examiner provisionally rejected both of Jang's independent claims for obviousness-type double patenting in view of Jang's co-pending Application No. 08/824,142 (the "'142 Application") (Ex. K).⁵ The '142 Application had claims requiring "non-collinear" "loop

⁵ Obviousness-type double patenting comes into play to "preclude a second patent on an invention which 'would have been obvious from the subject matter of the claims in the first patent, in light of the prior art.'" Ortho Pharm. Corp. v. Smith, 959 F.2d 936, 940 (Fed. Cir.

slots," '021 patent at JFH 215-17.

In stating his rejection, the Examiner described both of Jang's independent claims in the '021 patent, without differentiating between them, as both requiring that "expansion strut pairs" in adjacent columns be "offset" from each other, i.e., as requiring that they not have a 180 degrees out-of-phase design (JFH 216-217):

This application claims a first expansion column comprising a plurality of expansion strut pairs, a second expansion column comprising a plurality of second column expansion strut pairs, a first connecting strut column comprising struts which connect the first column expansion strut pairs to the second column expansion strut pairs, and a second connecting strut column comprising connecting struts which connect the second column expansion strut pairs to a third expansion column, ***wherein the expansion strut pairs of the first expansion column are longitudinally offset from the expansion strut pairs of the second expansion column.*** (Emphasis added).

The Examiner concluded that the "offset" expansion strut pairs of the '021 claims as amended and the "non-collinear loop slots" of Jang's '142 Application refer to the same subject matter and that both require that "expansion strut pairs" in adjacent columns be "offset." The Examiner accordingly rejected both of the independent claims of the '021 application for obviousness-type double patenting (id.):

...[T]he referenced copending application [the '142 Application] and the instant application [the application for the '021 patent] are claiming common subject matter, as follows:

This application [for the '021 patent] claims [expansion columns with a plurality of expansion strut pairs], ***wherein the expansion strut pairs of the first expansion column are longitudinally offset from the expansion strut pairs of the second expansion column.***

Application No. 08/824,142 claims ... first column loop slots [that] are ... non-collinear to the second column loop slots. (Emphasis added).

1992), quoting In re Longi, 759 F.2d 887, 893 (Fed. Cir. 1985). Here, the Examiner described the obviousness-type double patenting rejection as "provisional" because it was based on a copending application, rather than a previously issued patent. JFH 215-217.

The Examiner's comments show that he understood the independent claims, as amended, as directed to a stent in which the "expansion strut pairs" in adjacent columns are "offset" from each other. *Id.* Dr. Jang responded by filing a terminal disclaimer, opting not to dispute this (entirely correct) analysis.

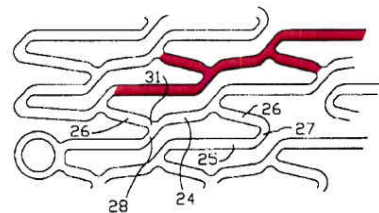
(b) The Examiner's Effort to Determine Whether the Provisional Application Disclosed Stents With Offset Expansion Strut Pairs in Adjacent Columns, Thus Entitling Jang's Independent Claims to an Earlier Priority Date Than Kanesaka

The last substantive episode in the '021 prosecution is described in the Examiner's Search Notes. JFH 57-59. That episode again shows that the Examiner understood the independent claims of the '021 patent as covering stents in which expansion struts pairs in adjacent columns are offset from one other.

The Search Notes show that on February 4, 1999, the Examiner conducted a search, JFH 57, and found three references – U.S. Patent Nos. 5,810,872 (Kanesaka) (Ex. L), 5,824,059 (Wijay) (Ex. M) and 5,836,964 (Richter) (Ex. N) – that had issued after his previous search on September 14, 1998. The Examiner listed these references in a "Notice of References Cited." JFH 228.

One of these references, Kanesaka '872, had connected expansion strut pairs in adjacent columns that are offset from one another and thus not 180 degrees out-of-phase. The Kanesaka reference had a filing date of March 14, 1997 – earlier than the April 25, 1997 filing date of the '021 patent and eleven days earlier than the March 25, 1997 filing date of the '021 patent's parent application.

FIG. 7



Kanesaka '872

The file history shows how the PTO addressed this issue. The Search Notes entry for February 4, 1999 states that the Assistant Examiner consulted with the Primary Examiner "regarding longitudinal offset columns in stent," JFH 57, i.e., expansion strut pairs in adjacent columns that have an offset or "split level" orientation. The Primary Examiner "[s]uggested comparing [Jang's] claims to [Jang's] provision[al] application, since ***patentability rests on the provisional data claimed in this application.***" Id. (emphasis added). The Search Notes then state that there ***"[n]eed[s] [to be a] basis for longitudinal offset columns in [the] provisional application [in order] for allowability."*** Id. (emphasis added). In other words, the Primary Examiner stated that it was necessary to determine whether the disclosure of Jang's April 1996 provisional application (JFH 1 et seq.) was sufficient to give Jang's independent claims an earlier priority date than Kanesaka because in the Examiner's view, patentability depended on whether Jang or Kanesaka was the first to design a stent with "offset" expansion strut pairs in adjacent columns.

The next and final entry in the Search Notes, dated February 10, 1999, states that after reviewing Jang's provisional application, the Assistant Examiner ***"[d]etermined that [it] ... has [a] basis for [claims directed to] longitudinal offsetting."*** Id. (emphasis added). In other words, the Assistant Examiner determined that Jang's provisional application disclosed stents in which the "expansion strut pairs" in adjacent columns had an "offset" configuration, thus entitling Jang's independent claims to an earlier priority date than Kanesaka. A Notice of Allowability issued the same day. JFH 226-27.

As this episode demonstrates, the allowance of claims 1 and 23 was predicated on the Examiner's understanding that the claims require "offset" or "split level" expansion strut pairs

in adjacent columns, and on the Examiner's finding that the provisional application showed that Jang had created this "split level" design earlier than Kanesaka.

C. New Extrinsic Evidence Reinforces Conor's Construction

1. BSC Has Admitted that Dr. Jang's "Invention" is a Stent That Has "Offset" Expansion Strut Pairs in Adjacent Columns

When the "wherein" clause was briefed before in this Court in the 03-027 case, BSC never admitted that Dr. Jang's invention was directed towards offset connected strut pairs. Nor did it admit that the wherein clause limited even claim 1 to that design. In the California case, however, BSC admitted that the offset connected strut pair was the point of novelty of Dr. Jang's invention and was required by claim 1.

The issue arose during the claim construction arguments in the California case. BSC's counsel there explained that Dr. Jang's "invention" was to connect "expansion strut pairs" that were "circumferentially offset." This was "clever" and an improvement over prior art stents whose connected strut pairs were "on the same plane," *i.e.*, 180 degrees out of phase:

[BSC's counsel]: And *let's talk about his invention*. First, we have expansion struts. They are attached circumferentially by joining struts [to create] expansion strut pairs when two [expansion] struts and put together with a joining strut. There are then connecting struts. *The connecting struts allow the expansion strut pairs to be circumferentially offset. If you look at the prior art patents, you have the [expansion] strut pairs that were on the same plane.*

What Dr. Jang did, and that was clever ... is to offset them.... That's the invention.

Ex. H at Tr. 72:17-73:5 (emphasis added). In response to a question from the Court, counsel elaborated with reference to a figure in the '021 patent:

If you look at the upper left-hand picture you see that *that strut pair, that horseshoe, is a little lower than the one above it*. . . . [T]here are advantages to that particular structure and Dr. Jang thought of that. *And*